

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A suspension of microcapsules in an aqueous liquid phase that allows modified release of at least one active principle and is intended for oral administration, wherein said suspension comprises a plurality of microcapsules and an aqueous liquid phase,

wherein the aqueous liquid phase is saturated or becomes saturated with active principle(s) on contact with the microcapsules, and

wherein each microcapsule comprises

(a) a core comprising at least one active principle(s), wherein none of the at least one active principle(s) is amoxicillin and

(b) a film coating that: (i) is applied to the core, (ii) controls the modified release of the active principle(s) in gastrointestinal tract fluids, and (iii) comprises:

(1) at least one film-forming polymer (P1) insoluble in gastrointestinal tract fluids, present in an amount of 50 to 90% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one film-forming polymer (P1) is a water-insoluble cellulose derivative;

(2) at least one nitrogen-containing polymer (P2) present in an amount of 2 to 25% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one nitrogen-containing polymer (P2) is selected from the group consisting of: polyacrylamide, poly-N-vinylamide, and poly-N-vinyl lactam;

(3) at least one plasticizer present in an amount of 2 to 20% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one plasticizer is selected from the group consisting of: glycerol esters, phthalates, citrates, sebacates, cetyl alcohol esters, and castor oil; and

(4) at least one surfactant or lubricant present in an amount of 2 to 20% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one surfactant or lubricant is selected from the group consisting of: anionic surfactants, non-ionic surfactants, and lubricants, and mixtures thereof;

and wherein the *in vitro* release profile on day ten of the suspension of microcapsules in an aqueous liquid phase is similar to the release profile on day zero, as measured using a type II apparatus according to the European Pharmacopoeia 3rd edition, in a phosphate buffer medium of pH 6.8, at a temperature of 37°C.

2. (Currently Amended) The suspension according to claim 1, wherein
at least one of the at least one film-forming polymer (P1) is selected from the group consisting of ethyl cellulose and cellulose acetate;
at least one of the at least one nitrogen-containing polymer (P2) is selected from the group consisting of polyacrylamide and polyvinylpyrrolidone;
at least one of the at least one plasticizer is castor oil;
at least one of the at least one surfactant or lubricant is selected from the group consisting of: an alkali metal ~~earth-metal~~-salt of fatty acids, , stearic acid, oleic acid, a polyethoxylated sorbitan ester, a polyethoxylated castor oil derivative, a stearate, ~~preferably calcium, magnesium, aluminium or zinc stearate~~, a stearyl fumarate, sodium stearyl fumarate, glycerol behenate, and mixtures thereof.
3. (Previously Presented) The suspension according to claim 1, wherein the film coating consists of a single layer.
4. (Previously Presented) The suspension according to claim 1, wherein said suspension comprises 30 to 95% by weight of liquid phase; and 5 to 70% by weight of microcapsules.
5. (Previously Presented) The suspension according to claim 1, wherein the proportion of dissolved active principle(s) originating from the microcapsules is less than or equal to 15% by weight of the total weight of the active principle(s) contained in the microcapsules.
6. (Cancelled)

7. (Previously Presented) The suspension according to claim 1, wherein the active principle(s) contained in the microcapsules saturates the liquid phase.

8. (Previously Presented) The suspension according to claim 1, wherein the aqueous liquid phase is at least partially saturated with active principle(s) by means of non-encapsulated active principle(s) prior to the incorporation of the microcapsules into the aqueous liquid phase.

9. (Previously Presented) The suspension according to claim 1 wherein the microcapsules have a particle size less than or equal to 1000 microns.

10. (Previously Presented) The suspension according to claim 1 wherein from 1 to 50% of the total weight of the coated microcapsules is film coating.

11. (Previously Presented) The suspension according to claim 10, having an *in vitro* release profile obtained using a type II apparatus according to the European Pharmacopoeia 3rd edition, in a phosphate buffer medium of pH 6.8 and at a temperature of 37°C, such that: the proportion PI of active principle(s) released during the first 15 minutes of the dissolution test is such that: $PI \leq 15$; and the remaining active principle(s) is (are) released over a period such that the release time of 50% by weight of AP ($t_{1/2}$) is defined as follows (in hours): $0.5 \leq t_{1/2} \leq 30$.

12. (Cancelled)

13. (Previously Presented) The suspension according to claim 1 wherein the pH of the suspension is arbitrarily acidic or neutral.

14. (Previously Presented) The suspension according to claim 1 wherein the suspension comprises at least one rheology modifier.

15. (Previously Presented) The suspension according to claim 1 wherein the suspension further comprises at least one agent for modifying the solubility of the active principle(s) in the aqueous liquid phase.

16. (Previously Presented) The suspension according to claim 1 wherein the suspension further comprises at least one additive selected from the group consisting of: surfactants, colourants, dispersants, preservatives, taste improvers, flavourings, sweeteners, antioxidants, and mixtures thereof.

17. (Previously Presented) The suspension according to claim 1 wherein at least one of the at least one active principle(s) is selected from the group consisting of: antiulcer drugs, antidiabetics, anticoagulants, antithrombics, hypolipidaemics, antiarrhythmics, vasodilators, antiangina drugs, antihypertensives, vasoprotectors, fertility promoters, labour inducers and inhibitors, contraceptives, antibiotics, antifungals, antivirals, anticancer drugs, anti-inflammatories, analgesics, antiepileptics, antiparkinsonism drugs, neuroleptics, hypnotics, anxiolytics, psychostimulants, antimigraine drugs, antidepressants, antitussives, antihistamines, and antiallergics; and wherein none of the at least one active principle(s) is amoxicillin.

18. (Previously Presented) The suspension according to claim 17, wherein at least one of the at least one active principle(s) is selected from the group consisting of: pentoxifylline, prazosin, aciclovir, nifedipine, diltiazem, naproxen, ibuprofen, flurbiprofen, ketoprofen, fenoprofen, indomethacin, diclofenac, fentiazac, oestradiol valerate, metoprolol, sulpiride, captopril, cimetidine, zidovudine, nicardipine, terfenadine, atenolol, salbutamol, carbamazepine, ranitidine, enalapril, simvastatin, fluoxetine, alprazolam, famotidine, ganciclovir, famciclovir, spironolactone, 5-asa, quinidine, perindopril, morphine, pentazocine, metformin, paracetamol, omeprazole, metoclopramide, atenolol, salbutamol morphine, verapamil, erythromycin, caffeine, furosemide, cephalosporins, montelukast, valaciclovir, ascorbic acid salts, diazepam, theophylline, ciprofloxacin, vancomycin, aminoglycosides, penicillins; and wherein none of the at least one active principle(s) is amoxicillin.

19. (Previously Presented) A drug comprising a suspension according to claim 1.

20. (Previously Presented) A kit for preparing the suspension according to claim 1, wherein said kit comprises:

microcapsules in substantially dry form-comprising the active principle(s) for saturating the liquid phase with active principle(s) once the solid form and liquid phase have been brought into contact;

a mixture of microcapsules in substantially dry form containing the active principle(s) in the dose that is just necessary for modified release, together with immediate-release uncoated active principle(s) in a necessary and sufficient dose to saturate the liquid phase with active principle(s) once the saturation dose of active principle(s) and the liquid phase have been brought into contact;

the liquid phase;

at least part of the ingredients useful for its preparation;

the protocol for preparation of the suspension; or

combinations thereof.

21. (Previously Presented) The suspension according to claim 4, wherein said suspension comprises 60 to 85% by weight of liquid phase.

22. (Previously Presented) The suspension according to claim 4, wherein said suspension comprises 15 to 40% by weight of microcapsules.

23. (Previously Presented) The suspension according to claim 1, wherein the proportion of dissolved active principle(s) originating from the microcapsules is less than or equal to 5% by weight of the total weight of the active principle(s) contained in the microcapsules.

24. (Previously Presented) The suspension according to claim 1 wherein the microcapsules have a particle size of between 200 and 800 microns.

25. (Previously Presented) The suspension according to claim 1 wherein the microcapsules have a particle size of between 200 and 600 microns.

26. (Previously Presented) The suspension according to claim 1 wherein from 5 to 40% of the total weight of the coated microcapsules is film coating.

27. (Previously Presented) The suspension according to claim 11, wherein the proportion PI of active principle(s) released during the first 15 minutes of the dissolution test is such that: $PI \leq 5$ and the remaining active principle(s) is (are) released over a period such that the release time of 50% by weight of AP ($t_{1/2}$) is defined as follows (in hours): $0.5 \leq t_{1/2} \leq 20$.